

**REMARKS**

Reconsideration of the above-identified case is respectfully requested in view of the following remarks. Applicant believes the amendments made to the claims encompass the concerns discussed during the Interview on November 18, 2003.

Claims 1-16 and 19-35 are pending in the Application.

Claims 17-18 are cancelled from the Application.

Claims 1, 3, 11, 16, 19-20, 26-27, 29, 31, 33, and 35 are amended in the Application.

Applicant appreciates the withdrawal of the double patenting rejection cited in the previous Office Action.

**I. Claim Amendments Discussed in the Interview on November 18, 2003**

Applicant has amended Claims 1, 3, 26-27, 29, 31, and 33 in order to recite the limitations of Claim 17. The amendment clarifies that the encapsulation agent encapsulates the capsaicin and that the encapsulation agent is colloidal oatmeal or a dipotassium glycyrrhizinate. Support for this amendment can be found on Page 8, Lines 6-28 of the Specification as filed. Per the Interview, Applicant believes this amendment overcomes the LaHann reference.

Applicant has amended Claims 1, 3, 26-27, 29, 31, and 33 in order to recite the limitations of Claim 18. The amendment clarifies that the esters of amino acids is lauryl menthyl esters of amino acids. Support for this amendment can be found on Page 9, Lines 10-16 of the Specification as filed.

Applicant also submits an affidavit signed and attested to by inventor Teresa Leigh Barr stating that esters of amino acids exist in the form of lauryl menthyl esters of amino acids. Lauryl menthyl esters are sold in glycolic solutions and distributed by Barnett

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Products Corporation of 560 Sylvan Avenue, Englewood Cliffs, New Jersey 07632, United States, under the trade name Cryolidone. The signed affidavit has been included with this Response as Attachment A.

Claims 17 and Claim 18 are hereby cancelled from the Application.

Applicant has amended the claims in order to encompass the concerns discussed during the Interview on November 18, 2003. Applicant believes that no new matter has been added with these amendments.

Reconsideration of the claims is respectfully requested in light of these amendments and the remarks discussed herein.

## **II. Claim Amendments – Clerical Errors**

Applicant has amended Claims 1, 3, 11, 16, 19-20, 26-27, 29, 31, 33, and 35 to correct some spelling and punctuation errors.

In Claims 1 and 3, Applicant has moved the period to the end of the claim.

In Claim 11, Applicant has added the period at the end of the claim.

In Claims 26, 27, 29 and 31, Applicant has replaced the colon after the encapsulation agent with a semi-colon. Applicant has also moved the period to the end of the claim. Applicant has also amended the last element in each claim to read properly as a lower case noun.

Further in Claim 29, Applicant has replaced the period in the preamble with a semi-colon.

In Claim 33, Applicant has inserted semi-colons to separate the elements of the claimed transdermal application.

In Claims 33 and 35, Applicant has corrected the spelling of the word

"comprising".

Applicant has amended these claims to correct clerical errors. Applicant believes that no new matter has been added with these amendments.

### III. Claim Rejections - 35 USC 112

The Office Action rejected Claim 16 under 35 USC 112 for being indefinite for failing to point particularly and to claim distinctly the subject matter because the claim is incomplete. Applicant has amended Claim 16 to read as originally filed to correct a clerical error from the Response filed on February 5, 2003. The amended Claim 16 includes the amendment to correct the dependency as requested in the Office Action with a November 6, 2002, mailing date.

Reconsideration of Claim 16 is respectfully requested.

### IV. Claim Rejections - 35 USC 103

The Office Action rejected Claims 1-5, 11-25, 30, 32, 34, and 35 under 35 USC 102(b) as being anticipated by LaHann US Patent No. 4,546,112 in view of Ishiwatari US Patent No. 6,074,652.

LaHann teaches the use of a capsaicin to prevent or reduce dermal irritation caused by a particularly agent known as a thioglycolate depilatory. Lahann claims a method for using capsaicin and salts of capsaicin directly on a depilated area. In weight percents, LaHann claims 0.5% of the capsaicin or salt of capsaicin and between 1% and 2% capsaicin.

The use of LaHann to put capsaicin on the skin to stop irritation is not the purpose of Applicants' invention. Applicant use of capsaicin is to promote a sense of "heat" into the joints of a patient. As stated in Page 4, Lines 16-17 of the Specification as filed, the

composition is made from "a carrier, capsaicin, an encapsulation agent, and ester of amino acid and a light diffusing compound."

Applicant's invention is designed to have two features that LaHann does not contemplate. First, Applicant's invention has the ability to reduce "secondary burning effect by the capsaicin due to the suns rays" as stated on Page 4, Lines 28-29 of the Specification as filed. LaHann does not contemplate this effect.

Second, Applicant's invention has the capsaicin encapsulated in the encapsulation agent, which is typically colloidal oatmeal as described on Page 8, Lines 6-19 of the Specification as filed. Other encapsulation agents are usable as well. For example, hydrogenated lecithin and dipotassium are used as encapsulation agents and not as surfactants. The LaHann reference does not suggest or encourage the use of any encapsulation agent.

Applicant has amended Claims 1, 3, 26-27, 29, 31, and 33 in order to recite the limitations of Claim 17. The amendment clarifies that the encapsulation agent encapsulates the capsaicin and that the encapsulation agent is colloidal oatmeal or a dipotassium glycyrrhizinate. Support for this amendment can be found on Page 8, Lines 6-28 of the Specification as filed. Per the Interview, Applicant believes this amendment overcomes the LaHann reference.

More specifically, after describing that the capsaicin is a dermatologically acceptable amount, the LaHann reference specifically states that "the balance of the composition comprises a dermatologically acceptable carrier." Further, the LaHann reference states that "suitable carriers ...preferably remain in place on the skin as a continuous film and resist being washed off easily. Finally, the LaHann reference states that "lotions, creams, solutions and gels are common physical forms of such compositions." These statements from the LaHann reference can be found in Column 3, Lines 19 - 29 of the patent. Without the encapsulation agent and the light scattering benefit, the synergistic effect of the invention would be lost.

Applicant believes that the Ishiwatari reference does not teach adding the missing

element from LaHann that the encapsulation agent for the capsaicin is a colloidal oatmeal or a dipotassium glycyrrhizinate.

Further, Ishiwatari teaches the use of ultra-violet absorbers as being compatible with capsaicin. Absorption is not desired by Applicant's formulation. In contrast, Applicants' formulation desires the deflection of light. The use of the light scattering component causes the sun rays to be deflected, so that secondary burning does not occur with the topical formulation. This is an important benefit of the invention.

According to the *American Heritage Dictionary*, to absorb means "to retain wholly, without reflection or transmission, that which is taken in." The Ishiwatari reference retains the ultra-violet and does not deflect the energy. The Applicant's formulation uses light scattering agents in order to not absorb the ultra-violet. Even if the Ishiwatari reference describes using titanium dioxide, the use in the Ishiwatari reference is for absorbing light, not scattering light.

Applicant notes the following from the Specification as file concerning the light scattering components of in the formulation:

"Titanium dioxide is considered the best light scattering element for the present invention". (See Page 10, Line 6 of the Specification as filed).

"Any of the Solaviel TiO<sub>2</sub> products for cosmetic use can be used. All will reflect[s] ultraviolet light and provide broad UVB light protection, effectively scattering the light rays. In a preferred embodiment, the TiO<sub>2</sub> can provide a complete block of sunlight and when mixed with the colloidal oatmeal, the light waves can be refracted and the skin protected from burning from the light." (See Page 10, Lines 10 -14 of the Specification as filed).

Even if the absorbers of Ishiwatari reference are construed similar to the light scattering components of Applicant's formulation, the Ishiwatari reference does not teach using an encapsulation agent around the capsaicin. The encapsulation component of Applicant's formulation encapsulates the capsaicin to reduce irritation while promoting the effect of warm to the skin. Ishiwatari reference focuses on creating an oil-in-water

emulsified composition of a glyceryl ether, a wax, a silicon oil, and, as taught in Claim 12, a film forming agent and a UV protecting agent

Reconsideration of the rejection of the claims that require the light scattering component, the encapsulation agent, and the capsaicin is respectfully requested.

The Office Action rejected further rejected Claims 6-10, 26, 28 and 33 under 35 USC 103 (a) in view of LaHann US Patent No. 4,546,112 in view of Ishiwatari US Patent No. 6,074,652 and in further view of Fourman US Patent No. 4,963,591.

Applicant believes that the Fourman reference does not teach adding the missing element from LaHann that the encapsulation agent for the capsaicin is a colloidal oatmeal or a dipotassium glycyrrhizinate.

Further, Fourman discusses the use of an arthritis lotion that makes a film and uses histamine dihydrochloride, capsaicin, and menthol. Fourman does not add the use of light scattering as a component. Forman also does not teach or suggest the use of an encapsulating agent, such as colloidal oatmeal, with capsaicin, he teaches making a film. Formula 10 of the Fourman reference does not discuss using capsaicin with an encapsulating agent. Formula 11, 12, and 13 of the Fourman reference does not teach using titanium dioxide. Formula 14 of the Fourman reference does not teach an encapsulating agent in the composition, but for the first time does teach using capsicum. Formulas 15, 16, 17, 18, 19 and 20 of the Fourman reference do not teach the use of encapsulating agents with capsaicin or capsicum. A film which is a layer does not act like a lotion, gel or cream with an encapsulating agent all around the capsaicin.

Reconsideration of the claims that require the use of capsaicin, an encapsulating agent, and light reflecting components is respectfully requested.

The Office Action rejected Claims 2, 27, 29 and 31 under 35 USC 102(b) as being anticipated by LaHann US Patent No. 4,546,112 in view of Ishiwatari US Patent No. 6,074,652) and in further view of McCleane US Patent No. 6,221,915 B1.

Applicant believes that the McCleane reference does not teach adding the missing

element from LaHann that the encapsulation agent for the capsaicin is a colloidal oatmeal or a dipotassium glycyrrhizinate.

Further, McCleane teaches in Example 3, Column 9 using:

- (a) capsaicin; with
- (b) glyceryl trinitrate, lanolin, paraffin, lactose, Sorbitol, cetyl alcohol, Isopropyl myristate, glyceryl stearate, PED stearate, and benzyl alcohol and water.

None of the elements listed in paragraph (b) of Example 3 are encapsulation agents. The McCleane reference does not suggested that any of these listed elements are for encapsulating the capsaicin.

Similarly, in Example 5 of the McCleane reference, the components are:

- (a) capsaicin; with
  - (b) lanolin, paraffin, Sorbitol, cetyl alcohol, isopropyl myristate, glyceryl stearate, PEG 100 stearate, benzyl alcohol and water.
- Again, as in

Again, none of the elements listed in paragraph (b) of Example 5 are encapsulation agents. The McCleane reference does not suggest that any of these listed elements are for encapsulating the capsaicin not that any of the listed elements are light scattering agents. Further, McCleane teaches in Examples 3 and 5 the use of a homogenous mixture. Applicants encapsulated mixture can not be homogeneous.

Even if the LaHann reference was combined with the Ishiwartari and McCleane references, the formulation of the capsaicin with an encapsulating agent with the light scattering component is not taught nor suggested by the combination.

Reconsideration of this application with the amended claim is respectfully requested.

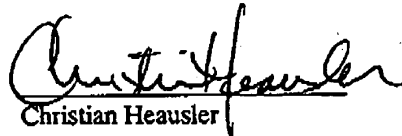
The cited references are noted.

Applicant duly appreciates Examiner Padmanabhan's and Examiner Kim's time and attention to this matter.

Respectfully submitted,

November 21, 2003

Date



Christian Heausler  
Patent Attorney  
Reg. No. 50,771

for

Wendy K. Buskop  
Patent Attorney  
Reg. No. 32,202

Please mail correspondence to:

Wendy K. Buskop  
Buskop Law Group, P.C.  
1717 St. James Place, Suite 500  
Houston, Texas 77056  
713.403.7411

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# **ATTACHMENT A**

## **AFFIDAVIT**

## PATENT

**UNITED STATES PATENT AND TRADEMARK OFFICE**

<b>Inventor:</b>	<b>Teresa Leigh Barr and Stephen D. Holt</b>	<b>Art Unit</b>	<b>1617</b>
<b>Appl. Serial No.:</b>	<b>09/534,953</b>	<b>Confirmation No.</b>	<b>1956</b>
<b>Filed:</b>	<b>March 24, 2000</b>	<b>Examiner:</b>	<b>Jennifer M. Kim</b>
<b>Title:</b>	<b>Pain Reliever and Method of Use</b>	<b>Att. Dkt. No:</b>	<b>310.18</b>

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

**AFFIDAVIT**

I, Teresa Leigh Barr, of 1730 Landes Street, Port Townsend, WA 98368, United States, Co-Inventor of the above referenced Patent Application do hereby declare that:

1. Esters of amino acids exist in the form of lauryl menthyl esters of amino acids. They are sold in glycolic solutions and distributed by Barnet Products Corporation of 560 Sylvan Avenue, Englewood Cliffs, New Jersey 07632, United States, under the trade name Cryolidone, the CTFA name is lauryl menthyl PCA.
2. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with knowledge that willful statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application and any registration resulting therefrom.

Co-Inventor

Dated: November 18, 2003

Signature: Teresa Leigh Barr

Printed Name: Teresa Leigh Barr

Telephone: 360.385.4825